

**RULES OF
GEORGIA DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION DIVISION
REVISE CHAPTER 111-8-10-.03
RULES FOR CLINICAL LABORATORIES**

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Georgia Department of Community Health proposes to revise the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10-.03, in response to the adoption of SB 273 which modifies the existing statutory definition of clinical laboratory to exclude laboratories which are nondiagnostic only and are regulated pursuant to the federal Clinical Laboratory Improvement Amendments. The Department is also proposing that the number of clinical laboratories a laboratory director is licensed to oversee be increased from three (3) to five (5). These changes are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. § 31-6-21 and O.C.G.A. § 31-6-21.1.

MAIN FEATURE OF THE PROPOSED RULE: Revision of the definition of clinical laboratory in accordance with the requirements of Senate Bill 273. Revision of the laboratory director requirements to increase the number of laboratories a laboratory director is licensed to oversee from three (3) to five (5) in line with federal laboratory regulations.

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**CHAPTER 111-8
HEALTHCARE FACILITY REGULATION**

**111-8-10
LICENSURE OF CLINICAL LABORATORIES**

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111-8-10-.03 Definitions

111-8-10-.03 Definitions. Amended.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) **Clinical Laboratory** means a facility for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from or produced by the human body for the diagnosis of, recommendation of, treatment of, or for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, the term "Clinical Laboratory" shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its components as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings; The term 'clinical laboratory' shall not include laboratories which are nondiagnostic only and regulated pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) whose sole function is to perform examination of human blood or blood components intended as source material for the manufacture of biological products.

**111-8-10-.06 Laboratory Personnel Requirements,
Personnel Qualifications and Personnel Records.**

...

(2) Licensed Laboratory Directors.

(a) Responsibilities and general requirements:

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4. Each licensed clinical laboratory must be served by a licensed clinical laboratory director, (permitted to direct no more than ~~three~~ five clinical laboratories at a given time), on a full time or regular part-time basis. However, no licensed clinical director (Restricted) shall be permitted to direct more than one clinical laboratory at a given time.